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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/469,738	12/21/1999	JOSEPH J. CHANG	056301.P478	5325

8791 7590 05/02/2003

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[REDACTED] EXAMINER

HAYES, MICHAEL J

ART UNIT	PAPER NUMBER
3763	15

DATE MAILED: 05/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/469,738	CHANG, JOSEPH J.	
	Examiner	Art Unit	
	Michael J Hayes	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 24 February 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 14-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 14-19 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 07 October 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the moveable member coupled to the blunting member and engaging the outer surface of the introducer sheath which advances the blunting member when the sheath is removed must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "16" and "30" have both been used to designate the cannula or the sheath.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification/Drawings

The disclosure is objected to because the cannula 30 and the sheath 16 are the same element though disclosed as a sheath 16 that includes a cannula 30. This double naming of an element introduces confusion. Applicant should give a single name and identifying reference numeral to the each element if applicable.

In Paper No. 12, received 1/28/03, Applicant states that cannula 30 may extend into the hub 37 and therefore sheath 16 refers only to that section of cannula 30 that extends out of the hub. Applicant's reliance on possibilities does not clarify the issue. Nowhere in the

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specification or drawings does Applicant describe or show cannula 30 extending into hub. As disclosed, Applicant is identifying a single element as separate elements.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: there is no antecedent basis for “moveable member” in the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 14-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. New matter appears to be recited in claim 14 which recites a moveable member coupled to the blunting member and engaging an outer surface of the introducer sheath where the moveable member advances the blunting member when the sheath is removed. The advancing of the blunting member with such a moveable member was not previously described in the application.

Claims 14-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not enabling for how the blunting member is moved relative to the needle. The drawings and

specification teach that the blunting member is secured to the housing 67 via securing member 75/77 and the needle 18 is attached to the housing 67 at the distal end of the housing 67. See figs. 1, 3, 4-6. Since both the needle and the blunting member are coupled to the housing and there is no separate moveable member separately accessible from the housing attached to the blunting member it appears that the needle and blunting member will move together and not respective to each other.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over GOMEZ (EP 0 630 661) in view of SAHI (U. S. Patent No. 5,009,642) and CHANG (U. S. Patent No. EP 0 353 905). Gomez discloses a catheter unit including an introducer sheath 72, needle 76, and flash chamber 78 having a flash plug 80. Gomez does not disclose a hollow blunting member fitting within the needle bore, a porosity for the flash plug, or a moveable member coupled to a blunting member and engaging an outer surface of the introducer sheath for advancing the blunting member. Sahi teaches the use of a hollow blunting member to protect against needle injury and to communicate with a flash chamber where a moveable member 22 is coupled to the blunting member and engages the outer surface (i.e., surface of 42b) of the introducer sheath 40 (Figs. 2-5). It would have been obvious to one of ordinary skill in the art at the time of the

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invention to use the blunting member and moveable member of Sahi in the device of Gomez in order to provide safe and accurate use of the medical device to prevent accidental injury due to the needle. Chang teaches the use of a UHMWPE flash plug with various porosities within the range of 35-55% (pg. 4, Table; claim 9) to provide for rapid filling of the flash chamber and thorough sterilization. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the porosities as taught by Chang in the catheter unit of Gomez and Sahi in order to provide a sterilizable device with efficient flash chamber.

Conclusion

Applicant stated in Paper No. 12 that all claims were presented in clean form in the submitted paper; however, no such claims are found with Paper No. 12. Applicant is requested to resubmit a clean version of all pending claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9302. The fax number for submitting after final papers is (703) 872-9303.



MICHAEL J. HAYES
PRIMARY EXAMINER

mjh
1 May 2003